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## **I. Status Of the Claims**

Claims 1-35 are currently pending in this Application. In the Final Office Action mailed on May 15, 2009, the Examiner rejected claims 1-4, 6-12, 18, 19, 21-26, 27, 29, 31, and 34 under U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,053,003 to Dadson et al. ("*Dadson*") in view of U.S. Patent No. 4,999,885 to Lee ("*Lee*"); rejected claims 5, 13, 15-17, 20, 30, 32, and 33 under U.S.C. § 103(a) as being unpatentable over *Dadson* in view of *Lee*, and further in view of U.S. Patent No. 5,820,582 to Keilman ("*Keilman*"); rejected claim 14 under U.S.C. § 103(a) as being unpatentable over *Dadson* in view of *Lee*, and further in view of U.S. Patent No. 4,772,497 to Maasola ("*Maasola*"); and rejected claim 35 under U.S.C. § 103(a) as being unpatentable over *Dadson* in view of *Lee*, and further in view of U.S. Patent Publication No. 2002/0115795 to Shang et al. ("*Shang*").

## **II. The Rejection of Claims 1-4, 6-12, 18, 19, 21-26, 27, 29, 31, and 34 under U.S.C. § 103(a) is Legally Deficient Because the Examiner Did Not Establish a Prima Facie Case of Obviousness**

Applicant traverses the 35 U.S.C. § 103(a) rejections of claims 1-4, 6-12, 18, 19, 21-26, 27, 29, 31, and 34 based on *Dadson* and *Lee*. The Examiner has failed to establish a prima facie case of obviousness by improperly determining the scope and content of the prior art and failing to properly identify the differences between the prior art and the claimed invention. Applicant submits that the combined prior art fails to disclose the subject matter recited in independent claims 1 and 27.

Claim 1, for example, recites a package for use in a peritoneal dialysis treatment comprising, among other things, "organizing means configured to organize the line set within the package during sterilization such that no part of the line set extends across another part of the line set during sterilization of the package" (emphasis added).

The Examiner relies on the *Dadson* for disclosing “a device for use in a peritoneal dialysis treatment (Abstract, line 1), wherein the package (Col. 5, line 61) includes a line set fully capable of being non-sterile . . . wherein the package is configured to substantially eliminate the risk of damage to the package or line set during sterilization, since the line set has been disclosed as supplied in sterile condition in a single PD package (Col. 5, lines 64, 65).” (Office Action at 4.) Applicant disagrees with the Examiner’s characterization of *Dadson*. The “package” the Examiner relies on in *Dadson* is only mentioned in two lines in the entire patent and is not sufficiently described or enabled. Nor is this “package” depicted in any of the figures in *Dadson*. *Dadson* merely discloses that “[o]ne form of this invention is constituted by a package which contains the “Y” set. . . . All these are supplied in sterile condition in a single PD package.” (Col. 5, lines 61-65.) Thus, while *Dadson* discloses that a sterile line set could be provided to a user in a package, *Dadson* does not disclose that a non-sterile line set could be placed in such a package and then safely sterilized, as the Examiner suggests and as recited in claim 1 of the present invention. One skilled in the art would not read *Dadson* as teaching a technique for sterilizing a line set contained within a package, because *Dadson* does not enable one skilled in the art to carry out such a sterilization technique. *Dadson* merely provides a particular line set, which may be placed, already sterilized, in a package for use by a doctor or patient. Accordingly, the Examiner has mischaracterized the scope and content of *Dadson*, and because *Dadson* fails to disclose all of the elements of claim 1 of this invention, this § 103 rejection based on *Dadson* as the primary reference should be withdrawn.

The Examiner further concedes that “Dadson does not expressly disclose the organizing means connected to both first and second tubular elements and arranged to organize the line set such that no part of the line set extends across another part of the line set.” (Office Action at 5.) The Examiner, however, attempts to use *Lee* to overcome the deficiencies of *Dadson*. Applicant contends that the Examiner’s proposed modification of *Dadson*, by using *Lee*, to allegedly obtain the claimed invention is improper and legally insufficient. See *Ex parte Whelan*, Appeal no. 2007-4423, 2008 WL 2957928 (BPAI July 23, 2008) (expanded panel) (for obviousness, it must be shown that one of ordinary skill in the art would have had some reason to modify a known product in the fashion claimed). No rational reason exists, nor has the Examiner properly provided such a reason, as to why one skilled in the art would have modified the line set of *Dadson* to obtain a package containing a line set organized in a manner to avoid damage to the line set during sterilization. As discussed above, the line set of *Dadson* is disclosed as being provided already sterilized and *Dadson* fails to disclose a technique for sterilizing a line set or a package containing a line set. Thus, the Examiner’s proposed modification of *Dadson* with *Lee* is insufficient to establish a prima facie case of obviousness and this § 103 rejection should be withdrawn.

As discussed above, the Examiner relies on *Lee* to overcome deficiencies of *Dadson*. In particular, the Examiner contends that “the clip of *Lee* defines the disposition of the tube elements within the same plane that provides the condition of reciprocal non-crossing of the tubular elements, and therefore the clip of *Lee* is fully capable of being arranged to organize the line set such that no part of the line set extends across another part of the line set (See Figs. 7-10).” (Office Action at 2.)

Applicant disagrees. *Lee* does not in fact, teach, disclose, or suggest “that no part of the line set extends across another part of the line set,” as recited in independent claim 1. As seen in Figs. 7 and 10, for example, a clip of *Lee* only even arguably prevents crossing of the tubes at a single location (i.e., the location of the clip).

Tubes secured by a clip of *Lee* could cross at a location up or down the line from the clip. Moreover, the Examiner’s contention that the clip of *Lee* is “capable” of being arranged as according to Applicant’s invention, is improper and merely highlights the fact that this claim element is not disclosed in *Lee*. In fact, *Lee* does not disclose this alleged capability, nor does *Lee* discuss that the crossing of portions of the line set should even be avoided. One skilled in the art reading *Lee* would not be concerned with the crossing of portions of the line set, because the clip of *Lee* is only disclosed as part of a line set being used by a patient, and not being sterilized in a package. The Examiner clearly fails to give proper weight to the organizing means recited in claim 1, which is configured to “organize the line set within the package during sterilization such that no part of the line set extends across another part.” In addition to mischaracterizing *Lee*, Applicant submits that the Examiner has misunderstood the claimed invention.

In the Advisory Action mailed September 9, 2009, in disagreeing with Applicant’s position, the Examiner contends that “claim [1] requires that no part of the line set extends across another part of the line set, but does not require that the tubes cannot cross.” Applicant fails to see the distinction and submits that the language recited in claim 1 can only logically be interpreted to require that the tubes cannot cross. Thus, *Lee* fails to disclose the organizing means recited in claim 1. For at least the above reasons, claim 1 is allowable over *Dadson* and *Lee*. Similar to claim 1, claim 27 recites,

“the step of organizing the line set within the package such that no part of the line set extends across another part of the line set during sterilization of the package,” and claim 27 is allowable for at least the same reasons as presented above with respect to claim 1

Accordingly, dependent claims 2-4, 6-12, 18, 19, 21-26, 29, 31, and 34 are allowable at least due to their dependence from allowable claims 1 and 27 and due to their additional recitations of novel subject matter.

**III. The Rejections of Claims 5, 13-17, 20, 30, 32, 33, and 35 under 35 U.S.C. § 103(a) are Legally Deficient Because the Examiner Did Not Establish a Prima Facie Case of Obviousness**

Applicant traverses the 35 U.S.C. § 103(a) rejections of claims 5, 13-17, 20, 30, 32, 33 and 35 under 35 U.S.C. § 103(a) as being unpatentable over *Dadson*, *Lee*, and *Keilman*, *Maasola*, or *Shang*. Applicant respectfully submits that the Examiner has failed to establish a prima facie case of obviousness. Claims 5, 13-17, 20, 30, 32, 33 and 35 depend from either claim 1 or claim 27, which, as discussed above are allowable over *Dadson* and *Lee*. *Keilman*, *Maasola*, or *Shang* fail to overcome the above-mentioned deficiencies of *Dadson* and *Lee* with respect to claims 1 and 27. Thus, claims 5, 13-17, 20, 30, 32, 33 and 35 are allowable at least due to their dependence from claims 1 and 27 and due to their additional recitations of novel subject matter.

**IV. Conclusion**

For the foregoing reasons, in addition to the reasons provided in the papers filed February 4, 2009 and August 12, 2009, Applicant respectfully submits that the rejection of claims 1-35 includes factual and legal deficiencies entitling Applicant to a pre-appeal brief review of the Final Office Action. Applicant requests that the rejections be withdrawn and the claims allowed. Please grant any extensions of time required to enter this response and charge any additional fees to our deposit account No. 06-0916.